Complete Summary

GUIDELINE TITLE

The management of erectile dysfunction: an update.

BIBLIOGRAPHIC SOURCE(S)

Erectile Dysfunction Guideline Update Panel. The management of erectile dysfunction: an update. Baltimore (MD): American Urological Association Education and Research, Inc.; 2005. Various p. [78 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: American Urological Association (AUA), Erectile Dysfunction Clinical Guidelines Panel. Report on the treatment of organic erectile dysfunction. Baltimore (MD): American Urological Association, Inc; 1996 Jul. 73 p. (Clinical practice guidelines; no. 7/96).

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory information has been released.

On July 8, 2005, the U.S. Food and Drug Administration (FDA) notified healthcare professionals of updated labeling for Cialis, Levitra, and Viagra to reflect a small number of post-marketing reports of sudden vision loss, attributed to NAION (non arteritic ischemic optic neuropathy), a condition where blood flow is blocked to the optic nerve. FDA advises patients to stop taking these medicines and call a doctor or healthcare provider right away if they experience sudden or decreased vision loss in one or both eyes. Patients taking or considering taking these products should inform their health care professionals if they have ever had severe loss of vision, which might reflect a prior episode of NAION. Such patients are at an increased risk of developing NAION again. At this time, it is not possible to determine whether these oral medicines for erectile dysfunction were the cause of the loss of eyesight or whether the problem is related to other factors such as high blood pressure or diabetes, or to a combination of these problems. See the FDA Web site for further information.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Erectile dysfunction

GUIDELINE CATEGORY

Evaluation
Management
Treatment

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Surgery
Urology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To provide medical practitioners with a consensus of principles and strategies for the management of erectile dysfunction

TARGET POPULATION

Men who have erectile dysfunction after a well-established period of normal erectile function, whose erectile dysfunction is primarily organic rather than psychological in nature, and who have no evidence of hypogonadism or hyperprolactinemia

INTERVENTIONS AND PRACTICES CONSIDERED

Evaluation

1. Identification of comorbidities and psychosexual dysfunctions through sexual, medical, and psychosocial history
2. Laboratory tests
3. Focused physical examination
4. Prostate-specific antigen measurement
5. Rectal examination
6. Additional testing, such as testosterone level measurement, vascular and/or neurological assessment and monitoring of nocturnal erections

Management/Treatment

1. Educate patients regarding treatment options and associated risks and benefits
2. Manage risk factors for erectile dysfunction (e.g., lifestyle modifications to prevent or reverse erectile dysfunction [ED])
3. Consider comorbidities when managing patients with ED (e.g., provide appropriate management of patients with ED in the presence of cardiovascular disease)
4. Pharmacologic therapy
    - Phosphodiesterase type 5 (PDE5) inhibitors (sildenafil, tadalafil, and vardenafil)
    - Alprostadil intra-urethral suppositories
    - Intracavernous injection with alprostadil, papaverine, or phentolamine or combinations
5. Vacuum constriction devices
6. Surgery
    - Penile prosthesis implantation with preoperative administration of antibiotics
    - Vascular surgery (penile arterial reconstructive surgery)
7. Periodic follow-up of efficacy, side effects, and change in health status

Note: Guideline developers considered but did not recommend the following treatments for ED: trazodone, testosterone therapy, herbal therapies including yohimbine, topical therapies, and venous reconstructive surgery.

MAJOR OUTCOMES CONSIDERED

- Erectile function as measured by the International Index of Erectile Function (IIEF)
- Intercourse satisfaction
- Ability to have intercourse
- Return to normal function
- Adverse events

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

In addition to erectile dysfunction (ED), the Panel elected to address three topics relevant to erection, Peyronie's disease, priapism, and premature ejaculation. In the year 2000, MEDLINE® searches of English-language references on human subjects were initiated for each of the four topics. Search strategies ranged from very general to very specific. Citations identified through subsequent targeted searches, such as those specifically focused on individual treatments, and through Panel member suggestions also were added to the database. The erectile dysfunction portion of the searches spanned the years from 1994, when the final literature search for the 1996 Report was completed, to February 2004. The Panel continued to scrutinize key references that were identified up until the peer-review process.

A special review of herbal therapies was performed later in the guideline process since few citations on herbal therapies were initially extracted. The search for herbal therapies included non-English language journals with abstracts written in English.

NUMBER OF SOURCE DOCUMENTS

- 1,021 articles were subjected to a preliminary review and extraction
- 112 were selected for extraction
- 85 articles had acceptable data

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

A detailed meta-analysis of study outcomes was attempted. Difficulties were encountered in developing outcome estimates for all therapies because of study inconsistencies in patient selection and outcome measures, the lack of sufficient data, and the reporting of adjusted results. Given these problems with the data, the Panel ultimately decided that meta-analysis was inappropriate.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

After the evidence was extracted and tabulated, the Panel met several times, both face-to-face and by teleconference, to review the data. Based on the data review and subsequent identification of the data limitations, meta-analysis was not deemed to be appropriate except for the intra-urethral alprostadil suppositories. Even meta-analyzed intra-urethral therapy data were not considered applicable for inclusion in an outcomes table because the patient inclusion criteria biased the results. Thus, the Panel decided to present the results separately for each treatment. In reviewing the data on phosphodiesterase type 5 (PDE5) inhibitors, the panel determined that a comparison of the efficacy and side effects could not be done with presently available data. Studies directly comparing these drugs had not been published at the time of the final literature search. Attempts at developing a comparative outcomes table based on meta-analysis also failed due to inconsistencies in patient selection and incomparable patient populations.

The Panel developed guideline statements based on the limited data. As in the previous guideline, the present guideline statements were graded with respect to the degree of flexibility in application.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

A "standard" has the least flexibility as a treatment policy, a "recommendation" has significantly more flexibility, and an "option" is even more flexible. These three levels of flexibility are defined as follows:

1. Standard: A guideline statement is a standard if (1) the health outcomes of the alternative interventions are sufficiently well known to permit meaningful decisions, and (2) there is virtual unanimity about which intervention is preferred.
2. Recommendation: A guideline statement is a recommendation if (1) the health outcomes of the alternative intervention are sufficiently well known to permit meaningful decisions and (2) an appreciable but not unanimous majority agrees on which intervention is preferred.
3. Option: A guideline statement is an option if (1) the health outcomes of the interventions are not sufficiently well known to permit meaningful decisions or (2) preferences are unknown or equivocal.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

This text of the report was developed as a group process with Panel members and consultants writing various sections. The editor was responsible for unifying the sections and incorporating the changes into the multiple drafts. The Panel reviewed each draft and the proposed changes. Several drafts of the guideline were distributed before final Panel approval.

After Panel approval, a draft underwent peer review by 80 individuals, including members of the Practice Guidelines Committee, the American Urological Association (AUA) Board of Directors, and external experts in the management of erectile dysfunction (ED). Peer reviewers' comments were entered into a database that the Panel subsequently met to review. The Guideline was modified where the Panel deemed necessary in response to these comments. A final version of the report was generated and the Panel voted for approval. This version was then forwarded in turn for approval of the Practice Guidelines Committee and the American Urological Association Board of Directors.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Note from the National Guideline Clearinghouse: The recommendations without the associated supporting text have been excerpted from the guideline. For full context, please refer to the original guideline document.

Definitions of the strength of the recommendations (standard, recommendation, option) are defined at the end of the "Major Recommendations" field.

Initial Management and Discussion of Treatment Options with Patients

Recommended Therapies and Patient Information

Standard: The management of erectile dysfunction begins with the identification of organic comorbidities and psychosexual dysfunctions; both should be appropriately treated or their care triaged. The currently available therapies that should be considered for the treatment of erectile dysfunction include the following: oral phosphodiesterase type 5 (PDE5) inhibitors, intra-urethral alprostadil, intracavernous vasoactive drug injection, vacuum constriction devices, and penile prosthesis implantation. These appropriate treatment options should be applied in a stepwise fashion with increasing invasiveness and risk balanced against the likelihood of efficacy (based on review of data and Panel consensus).

Standard: The patient and, when possible, his partner should be informed of the relevant treatment options and their associated risks and benefits. The choice of treatment should be made jointly by the physician, patient, and partner, when possible, taking into consideration patient preferences and expectations and the experience and judgment of the physician (based on Panel consensus).

Treatment Guideline Statements

PDE5 Inhibitors

Standard: Oral PDE 5 inhibitors, unless contraindicated, should be offered as a first-line of therapy for erectile dysfunction (based on review of data and Panel consensus).

Standard: PDE5 inhibitors are contraindicated in patients who are taking organic nitrates (based on review of U.S. Food and Drug Administration [FDA]-approved product labeling and Panel consensus).

Recommendation: The monitoring of patients receiving continuing PDE5 inhibitor therapy should include a periodic follow-up of efficacy, side effects, and any significant change in health status including medications (based on Panel consensus).

Recommendation: Prior to proceeding to other therapies, patients reporting failure of PDE5 inhibitor therapy should be evaluated to determine whether the trial of PDE5 inhibition was adequate (based on Panel consensus).

Recommendation: Patients who have failed a trial with PDE5 inhibitor therapy should be informed of the benefits and risks of other therapies, including the use of a different PDE5 inhibitor, alprostadil intra-urethral suppositories, intracavernous drug injection, vacuum constriction devices, and penile prostheses (based on Panel consensus).

Alprostadil Intra-urethral Suppositories

Standard: The initial trial dose of alprostadil intra-urethral suppositories should be administered under healthcare provider supervision due to the risk of syncope (based on review of FDA-approved product labeling and Panel consensus).

Intracavernous Vasoactive Drug Injection Therapy

Standard: The initial trial dose of intracavernous injection therapy should be administered under healthcare provider supervision (based on Panel consensus).

Standard: Physicians who prescribe intracavernous injection therapy should (1) inform patients of the potential occurrence of prolonged erections, (2) have a plan for the urgent treatment of prolonged erections, and (3) inform the patient of the plan (See the National Guideline Clearinghouse [NGC] summary of the American Urological Association [AUA] guideline The Management of Priapism) (based on Panel consensus).

Vacuum Constriction Devices

Recommendation: Only vacuum constriction devices containing a vacuum limiter should be used whether purchased over-the-counter or procured with a prescription (based on Panel consensus).

Treatment Modalities With Limited Data

Trazodone

Recommendation: The use of trazodone in the treatment of erectile dysfunction is not recommended (based on review of the data and Panel consensus).

Testosterone

Recommendation: Testosterone therapy is not indicated for the treatment of erectile dysfunction in the patient with a normal serum testosterone level (based on Panel consensus).

Yohimbine

Recommendation: Yohimbine is not recommended for the treatment of erectile dysfunction (based on review of the data and Panel consensus).

Other Herbal Therapies

Recommendation: Herbal therapies are not recommended for the treatment of erectile dysfunction (based on review of the data and Panel consensus).

Surgical Therapies

Penile Prosthesis Implantation

Standard: The patient considering prosthesis implantation and, when possible, his partner should be informed of the following: types of prostheses available; possibility and consequences of infection and erosion, mechanical failure, and resulting reoperation; differences from the normal flaccid and erect penis, including penile shortening; and potential reduction of the effectiveness of other therapies if the device is subsequently removed (based on Panel consensus).

Standard: Prosthetic surgery should not be performed in the presence of systemic, cutaneous, or urinary tract infection (based on Panel consensus).

Standard: Antibiotics providing Gram-negative and Gram-positive coverage should be administered preoperatively (based on Panel consensus).

Vascular Surgery

Penile Venous Reconstructive Surgery

Recommendation: Surgeries performed with the intent to limit the venous outflow of the penis are not recommended (based on review of the data and Panel consensus).

Penile Arterial Reconstructive Surgery

Option: Arterial reconstructive surgery is a treatment option only in healthy individuals with recently acquired erectile dysfunction secondary to a focal arterial occlusion and in the absence of any evidence of generalized vascular disease (based on review of the data and Panel consensus).

Definitions:

Strength of Recommendations

1. Standard: A guideline statement is a standard if (1) the health outcomes of the alternative interventions are sufficiently well-known to permit meaningful decisions, and (2) there is virtual unanimity about which intervention is preferred.
2. Recommendation: A guideline statement is a recommendation if (1) the health outcomes of the alternative intervention are sufficiently well-known to permit meaningful decisions and (2) an appreciable but not unanimous majority agrees on which intervention is preferred.
3. Option: A guideline statement is an option if (1) the health outcomes of the interventions are not sufficiently well-known to permit meaningful decisions or (2) preferences are unknown or equivocal.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The recommendations are based on current professional literature, clinical experience, and expert opinion.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Overall Potential Benefit

Appropriate management and effective treatment of organic erectile dysfunction

POTENTIAL HARMS

- Sildenafil, tadalafil, and vardenafil have side effects due to peripheral vasodilation such as facial flushing, nasal congestion, headache, and dyspepsia. Both sildenafil and vardenafil, but not tadalafil, have some cross-reactivity with phosphodiesterase type 6 (PDE6) and thus may produce visual side effects. Tadalafil exhibits some cross-reactivity with PDE11, but there are no known side effects due to PDE11 inhibition at this time. Back pain has been reported in a limited number of patients, especially those taking tadalafil, and the pathophysiology of this adverse effect is unknown. A mild prolongation of the QT interval has been observed with vardenafil. The Food and Drug Administration (FDA)-approved product labeling for vardenafil recommends that caution be used when prescribing vardenafil in patients with a known history of QT prolongation or in patients who are receiving agents that prolong the QT interval.

- When considering PDE5 inhibitors for the management of erectile dysfunction (ED), physicians should be aware that even healthy volunteers may experience mild transient systemic vasodilation; this effect may be aggravated by alpha-blocking therapies.
- Hypotension has been reported to occur in approximately 3% of patients after the first dose of alprostadil.
- A healthcare provider should be present to instruct patients on the proper technique of intracavernous drug administration, to determine an effective dose, and to monitor patients for side effects, especially prolonged erection.
- In addition to mechanical failure, inflatable penile prostheses are associated with complications such as pump displacement and auto-inflation.
- Infection is a devastating complication of any prosthetic surgery. Currently available inflatable prostheses have been modified in an attempt to reduce the risk of infection.

CONTRAINDICATIONS

CONTRAINDICATIONS

- Vardenafil is contraindicated in all patients taking any medication with alpha-blocker activity.
- Phosphodiesterase type 5 inhibitors are contraindicated in patients who are taking organic nitrates.
- Magnetic resonance imaging (MRI) is contraindicated in patients with a ferromagnetic implant because of the risks associated with movement, dislodgement, induction of electrical current, excessive heating, and/or misinterpretation artifacts.
- Prosthetic surgery should not be performed in the presence of systemic, cutaneous, or urinary tract infection.

QUALIFYING STATEMENTS

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- Some of the medical therapies currently employed in the management of erectile dysfunction (ED) have not been approved by the U.S. Food and Drug Administration (FDA) for this specific indication. Thus, doses and dosing regimens may deviate from that employed for FDA-approved indications, and this difference should be considered in the risk-versus-benefit assessment. This document does not establish a fixed set of rules or define the legal standard of care and it does not pre-empt physician judgment in individual cases.
- The guideline developers decided against reviewing the data on testosterone, as it was beyond the scope of the guideline, and on apomorphine, which was not approved for use in the United States.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Erectile Dysfunction Guideline Update Panel. The management of erectile dysfunction: an update. Baltimore (MD): American Urological Association Education and Research, Inc.; 2005. Various p. [78 references]

ADAPTATION

Not applicable: Guideline was not adapted from another source.

DATE RELEASED

1996 (revised 2005)

GUIDELINE DEVELOPER(S)

American Urological Association Education and Research, Inc. - Medical Specialty Society

SOURCE(S) OF FUNDING

The American Urological Association (AUA) is the sole source of funding.

GUIDELINE COMMITTEE

Erectile Dysfunction Guideline Update Panel and Consultants

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Committee members received no remuneration for their work. Each member of the committee provided a conflict of interest disclosure to the American Urological Association (AUA).

GUIDELINE STATUS

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GUIDELINE AVAILABILITY

Electronic copies: Available from the American Urological Association, Inc. (AUA) Web site.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Chapter 1: the management of erectile dysfunction: an AUA update. J Urol 2005 Jul. 174:230-9.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on March 26, 1999. The information was verified by the guideline developer as of May 14, 1999. This NGC summary was updated by ECRI on July 20, 2005. The updated information was verified by the guideline developer on August 17, 2005.

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